

Eighth EDRN Steering Committee Meeting
June 23-25, 2003
University of Pittsburgh
Pittsburgh, PA

Monday, June 23, 2003

**WORKSHOP ON MOVING BIOMARKERS FROM VALIDATION TO THE
COMMERCIALIZATION PATHWAY**

WORKSHOP AGENDA

12:00-1:45 p.m. Moving Biomarkers from Validation to a Commercialization Pathway: Regulatory Requirements and Programmatic Objectives

Moderators: **Mukesh Verma, Ph.D.**, NCI EDRN Program Director
Wendy Patterson, Esq., NCI Technology Transfer Branch

12:00-12:10 p.m. Overview:
Wendy Patterson, Esq., NCI Technology Transfer Branch

12:10-12:30 p.m. Summary of FDA Requirements:
Steven J. Gutman, Ph.D., M.B.A., Director, FDA/CDRH Office of In Vitro Diagnostic Device Evaluation and Safety

12:30- 1:00 p.m. MSA Validation Study:
Mark Schoenberg, M.D., Johns Hopkins Medical Institution
Sigrid M. Volko, Ph.D., Assistant Director, Johns Hopkins University Office of Licensing and Technology Development
Robert Kalik, Esq., Cangen International Corp.

1:00 - 1:30 p.m. SELDI/Prostate Validation Study:
O. John Semmes, Ph.D., Eastern Virginia Medical School
[Senior Patent Counsel TBD], Esq., CIPHERGEN Biosystems, Inc.
William Grizzle, Ph.D., M.D., University of Alabama at Birmingham
Ian Thompson, M.D., University of Texas Health Science Center at San Antonio

1:30 - 1:45 p.m. Discussion

1:45 – 2:00 p.m. Break

2:00 -3:45 p.m. Intellectual Property Strategies for Commercialization of EDRN-Validated Biomarkers: Government, Academic, and Industry Perspectives

Moderators: **Jacob Kagan, Ph.D.**, NCI EDRN Program Director
Wendy Patterson, Esq., NCI Technology Transfer Branch

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(Continued)**

- 2:00 – 2:30 p.m. Government Perspective:
Wendy Patterson, Esq., Senior Advisor, NCI Technology Transfer Branch
J. Terry Lynch, M.B.A., Licensing Officer, NIST Technology Partnerships Division
- 2:30 – 3:00 p.m. Academic Perspective:

Elaine Brock, Esq., Director, University of Michigan Medical School Office of Technology Transfer & Corporate Research

Sigrid M. Volko, Ph.D., Assistant Director, Johns Hopkins University Office of Licensing and Technology Development

Dean E. Brenner, M.D., University of Michigan Medical Center

O. John Semmes, Ph.D., Eastern Virginia Medical School
- 3:00 – 3:30 p.m. Industry Perspective:

Bayer Corporation:
[Senior Patent Counsel TDB], Esq.
Peter J. Maimonis, Ph.D., Associate Director, Oncology Research
- Abbott Laboratories/Vysis:**
William E. Murray, Esq., Senior Counsel, Patents & Trademarks
Steven Seelig, M.D., Ph.D., Divisional Vice President, Research & Development
- Cangen International Corporation:**
Robert Kalik, Esq., Chief Operating Officer

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- 4:00-6:00 p.m. Subcommittee Meetings *(By Invitation Only)*
- 4:00-6:00 pm Discussion on Biorepository with Dr. Ann Barker, Deputy Director, NCI *(Closed Meeting, EC and all Chairs to Attend)*
- 6:00-7:00 p.m. Dinner
- 7:00-8:00 p.m. **Subcommittee and Liaison Reports**
SPORE Carolyn Muller
PCPT: Ian Thompson
AACR: William Bigbee
ASCO: Austin Doyle
CGN: Steven Skates
MMHCC: Jeffrey Marks

Tuesday, June 24, 2003

- 7:00-8:00 a.m. **Registration and Continental Breakfast**
- 8:00-8:30 a.m. **Introduction**
William Bigbee and University of Pittsburgh Officials
- 8:30-8:40 a.m. **Welcome & Approval of January 2003 SC minutes:**
David Sidransky
- 8:40-8:50 a.m. **Welcome**
Peter Greenwald
- 8:50-9:10 a.m. **NCI Update**
Sudhir Srivastava
- 9:10-9:30 a.m. **NCI Strategic Initiative**
Anna Barker
Deputy Director of the National Cancer Institute
- 9:30-9:40 a.m. **A Critique of the EDRN: Successes and Failures**
Bernard Levin
Chair, EDRN Network Consulting Committee
- 9:40-10:15 a.m. **Guest Lecture**
Cancer: What have we learned and how can we apply it?
Lee Hartwell
President and Director, Fred Hutchinson Cancer Research Center

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10:15-10:30 a.m. **Break**

10:30 a.m.–Noon **EDRN High Risk Cohorts: Resource for Validation Studies**

Moderators: Wendy Wang, Jacob Kagan

Speakers: Patrice Watson
Xifeng Wu (Margaret Spitz's laboratory)
William Rom
Ian Thompson
Sandra Hoffman (Kathy Helzlsouer's lab)
Daniel Cramer/ Ian Jacobs

12:00-1:00 p.m. Lunch
EC Meeting (Working Lunch) *by Invitation Only*

1:00-1:30 p.m. **Antibody Arrays**

Moderators: Jeffrey Marks, Jacob Kagan

Speaker: Brian Haab
Van Andel Research Institute

1:30-1:45 p.m. **Update: EDRN Antibody Array Project**
Jacob Kagan

1:45-2:15 p.m. **MALDI-TOF and Biomarker Discovery**
Yingming Zhao

2:15-5:00 p.m. **Collaborative Group Meeting (*by Invitation Only*)**

5:00 7:00 p.m. Dinner (On Your Own)

7:00-7:15 p.m. **Collaborative Group Reports**

7:15-9:00 p.m. **Collaborative Showcase: Prostate and Urologic Cancers Group**

Wednesday, June 25, 2003

7:00-8:00 a.m. **Continental Breakfast**

8:00-8:30 a.m. **Guest Speaker**
The proteome of DNA replication in cancer
Linda H. Malkas

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8:30-9:00 a.m. **MALDI/SELDI-TOF-MS proteomic profiling for cancer early detection and molecular diagnosis - summary of latest studies**

William L. Bigbee

9:00-10:30 a.m. **Highlights of the Associate Membership Program**

Moderators: Mukesh Verma, Wendy Wang

Speakers: Ying-Hsiu Su/Timothy Block, Thomas Jefferson University
Detection of tumor-related genetic and epigenetic modifications in urine

Edward Patz/Jeffrey Marks, Duke University
Expression Profiling with a MALDI-TOF Platform Identifies Serum Markers for Lung Cancer

Eleftherios Diamandis/Sudhir Srivastava, University of Toronto
An Update on Kallikreins as Cancer Biomarkers

Carolyn Muller, University of Texas, Dallas

David Bowtell/ Stephen Meltzer
Strategies for the development of biomarkers of gastric cancer

Mai Brooks/ David Chia
Angiogenesis and breast cancer detection and prevention

Panel Discussion: EDRN Associate Membership Program (AM) and its Accomplishments

Panelists: EDRN Sponsoring PIs

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9:00-10:30 a.m. **Highlights of the Associate Membership Program (Continued)**

Suggested topics for discussion:

1. Sponsor's interactions with AM, collaboration and benefits to EDRN
2. Specific examples in terms of resource sharing and or technology transfer
3. Suggestions to integrate AM in additional EDRN activities
4. How does AM benefit EDRN goals and vice versa

10:30-10:45 a.m. **Break**

10:45-11:00 a.m. **Administrative Issues**

11:00 a.m.-Noon **Update: EDRN Bioinformatics Infrastructure and Tools**

Moderators: Sudhir Srivastava, Donald Johnsey

Speakers: Daniel Crichton
 Mark Thornquist
 Heather Kincaid

12:00-1:00 p.m. **Lunch**

1:00-3:00 p.m. **EDRN Computational Tools for Biomarker Discovery and Validation**

Moderator: Sudhir Srivastava

Speakers: Steven Skates, Brigham and Women's Hospital
 Ziding Feng, Fred Hutchinson Cancer Center
 Zhen Zhang/Dan Chan, Johns Hopkins (Alan Partin's Group)
 UCLA (David Chia's Group)
 Florin Selaru/Stephen Meltzer, University of Maryland

3:00-3:15 p.m. **New Business**

3:15 p.m. **Adjourn**